Joint Disputed Claim Terms Chart C.A. No. 17-cv-01235-MRH – Western District of Pennsylvania U.S. Patent No. 9,643,997 ("'997 Patent")[1]				
Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
9. A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:	Not Disputed; Provided for Context			
(a) solubilizing the expressed protein in a solubilization solution comprising one or more of the following: (i) a denaturant; (ii) a reductant; and	Not Disputed; Provided for Context			

[1] Mylan reserves the right to assert additional evidence in rebuttal to Amgen's proposed constructions during briefing. To the extent Mylan is permitted to assert additional evidence in rebuttal to Amgen's proposed constructions, Amgen may present additional evidence in reply. The parties further intend to rely on the patents-in-suit, the specifications of the patents-in-suit, the claims of the patents-in-suit, the file histories of the patents-in-suit, and patents and applications to which the patents-in-suit claim priority, including related patents or patent applications. Any additional evidence or reference within or encompassed by a particular citation is deemed incorporated by reference (e.g., references to a figure or table are incorporated by reference).

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
(iii) a surfactant				
(b) **forming a refold solution comprising the solubilization solution and a refold buffer**, the refold buffer comprising one or more of the following: (i) a denaturant; (ii) an aggregation suppressor; (iii) a protein stabilizer; and (iv) a redox component;	mixing the solution comprising the solubilized protein and one or more of a denaturant, a reductant, and a surfactant with a pH-buffered solution comprising one or more of a denaturant, an aggregation suppressor, a protein stabilizer, and a redox component providing conditions for the protein to refold into its biologically active form	**'997 Patent** MYL(PegF)0145360-82, including but not limited to: col. 12:27-32; 13:65–14:3; 14:27-40; 15:5-13.	Mylan contends that no construction is necessary and that this term should be afforded only its plain and ordinary meaning. To the extent Amgen offers proposed constructions for any terms or phrases which differ from the person of ordinary skill in the art's understanding of the plain and ordinary meaning of any of the terms or phrases, Mylan reserves the right to offer alternative construction(s). (Shortened below to "plain and ordinary meaning; no construction necessary")	**'997 Patent** MYL(PegF)0145360-82, including but not limited to: 2:26-37; 14:28-30; 19:22-27; 20:46-50 *See also* Order Construing Claims at 21, *Amgen Inc. et al. v. Sandoz Inc. et al.*, No. 14-cv-04741-RS (N.D. Cal. Aug. 4, 2016) (ECF No. 205) (wherein no construction was proposed by Amgen)
(c) **applying the refold solution to a separation matrix** under conditions suitable for the protein	applying the refold solution to a column that contains the separation matrix without intervening steps of dilution, centrifugation, dialysis, or	**'997 Patent** MYL(PegF)0145360-82, including but not limited to:	"applying the refold solution to a separation matrix without removing components of or diluting the	Order Construing Claims at 20-25, *Amgen Inc. et al. v. Sandoz Inc. et al.*, No. 14-cv-04741-RS

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
to associate with the matrix;	precipitation	col. 12:14-20, 40-67. **'997 Patent File History** (App. No. 14/599,336) MYL(PegF)0145383-9670, including but not limited to: 3/1/2016 Response to Office Action at 11. **U.S. Patent No. 7,138,370** ("Oliner") including but not limited to: col. 76:44-61. **U.S. Patent No. 8,940,878** ("the '878 Patent") MYL(PegF)0149671-91, including but not limited to: Claim 7. **'878 Patent File History** (App. No. 12/822,990) MYL(PegF)0149692-	refold solution" Alternatively, plain and ordinary meaning; no construction necessary	(N.D. Cal. Aug. 4, 2016) (ECF No. 205) (construing phrase "directly applying the refold solution to a separation matrix")[2] **'997 Patent** MYL(PegF)0145360-82, including but not limited to: Abstract; 1:13-17; 2:21-37; 3:53-57; 4:52-5:6; 9:36-39; 12:11-20; 12:33-50; 15:50-67; 17:7-10 **'997 Patent Prosecution History** MYL(PegF)0145383-9670, including but not limited to: 10/2/2015 Office Action at 6-7 (MYL(PegF) 0145735-36);

[2] For all citations to the prior claim construction ruling in the related *Sandoz* litigation, Mylan incorporates by reference the intrinsic evidence considered by or relied upon by the Court in making that ruling.

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
		50772, including but not limited to: 1/9/2014 Amendment Response at 7-8.		3/1/2016 Response at 11-12 (MYL(PegF) 0145761-62) **'997 Parent Prosecution History** MYL(PegF)0149692-50772, including but not limited to: 1/25/2013 Response at 7-8 (MYL(PegF) 0150160-61); 9/9/2013 Office Action (MYL(PegF) 0150181-93); 1/9/2014 Response at 7 (MYL(PegF) 0150224)
(c) applying the refold solution to a separation matrix **under conditions suitable for the protein to associate with the matrix**;	under conditions suitable for protein to have specific, reversible interactions with a separation matrix in order to effect the separation of protein from its environment	**'997 Patent** MYL(PegF)0145360-82, including, but not limited to: col. 7:25-32; 10:45-50; 16:1-4.	"under conditions suitable for the protein to be purified to bind to the matrix" Alternatively, plain and ordinary meaning; no construction necessary	Order Construing Claims at 25-29, *Amgen Inc. et al. v. Sandoz Inc. et al.*, No. 14-cv-04741-RS (N.D. Cal. Aug. 4, 2016) (ECF No. 205) (construing phrase "under conditions

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
				suitable for the protein to associate with the matrix") **'997 Patent** MYL(PegF)0145360-82, including but not limited to: 3:16-18; 3:28-36; 7:25-37; 16:1-4; 16:24-28; 16:43-52; 16:60-67; 18:39-41; 19:39-40; 20:1-3; 21:10-14 **'997 Parent Prosecution History** MYL(PegF)0149692-50772, including but not limited to: 9/23/2010 Information Disclosure Statement at MYL(PegF) 0149781-92
(d) **washing the separation matrix**;	applying a solution to the column that contains the separation matrix, which	**'997 Patent** MYL(PegF)0145360-82, including, but not	"applying a solution to remove unbound protein, lysate, impurities, and	Order Construing Claims at 29-30, *Amgen Inc. et al. v.*

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
and	application has the effect of removing unbound protein, lysate, impurities, and unwanted components of the refold solution from the separation matrix while preserving interactions between the protein and the separation matrix	limited to: col. 10:45-50; 16:1-4.	unwanted components of the refold solution from the separation matrix while preserving binding of the expressed protein" Alternatively, plain and ordinary meaning; no construction necessary	*Sandoz Inc. et al.*, No. 14-cv-04741-RS (N.D. Cal. Aug. 4, 2016) (ECF No. 205) (construing phrase "washing the separation matrix") **'997 Patent** MYL(PegF)0145360-82, including but not limited to: 16:1-4; 16:5-18; 18:42-48; 19:41-46; 20:4-8; 20:63-21:3 **'997 Parent Prosecution History** MYL(PegF)0149692-50772, including but not limited to: 9/23/2010 Information Disclosure Statement at MYL(PegF) 0149781-92
(e) **eluting the protein from the separation**	applying a solution to the column that contains the	**'997 Patent** MYL(PegF)0145360-	"applying a solution that reverses the binding of the	Order Construing Claims at 30-31,

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
matrix.	separation matrix, which application has the effect of reversing the interactions between the protein and the separation matrix	82, including, but not limited to: col. 10:66–11:3; 16:19-28.	purified protein to the separation matrix" This step must occur after the step of "washing the separation matrix." Alternatively, plain and ordinary meaning; no construction necessary	*Amgen Inc. et al. v. Sandoz Inc. et al.*, No. 14-cv-04741-RS (N.D. Cal. Aug. 4, 2016) (ECF No. 205) (construing phrase "eluting the protein from the separation matrix") **'997 Patent** MYL(PegF)0145360-82, including but not limited to: 16:24-35; 18:42-48; 19:41-46; 20:4-8; 20:63-21:3 **'997 Parent Prosecution History** MYL(PegF)0149692-50772, including but not limited to: 9/23/2010 Information Disclosure Statement at MYL(PegF) 0149781-92

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
separation matrix	any adsorbent material that utilizes specific, reversible interactions between synthetic and/or biomolecules	**'997 Patent** MYL(PegF)0145360-82, including, but not limited to: col. 7:25-32.	Plain and ordinary meaning; no construction necessary Alternatively, if construction required: "any adsorbent material that utilizes specific, reversible interactions between synthetic and/or biomolecules, e.g., the property of Protein A to bind to an Fc region of an IgG antibody or other Fc-containing protein, in order to effect the separation of the protein from its environment. In other embodiments the specific, reversible interactions can be based on a property such as isoelectric point, hydrophobicity, or size."	**'997 Patent** MYL(PegF)0145360-82, including but not limited to: 7:25-32

Joint Disputed Claim Terms Chart C.A. No. 17-cv-01235-MRH – Western District of Pennsylvania U.S. Patent No. 8,273,707 ("'707 Patent")[3]				
Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
1. A process for purifying a protein on a **hydrophobic interaction chromatography column**	a column containing a matrix and a mobile or solution phase in which the hydrophobic interaction between a protein and hydrophobic groups on the matrix serves as a basis for separating the protein from impurities, including fragments and aggregates of the subject protein, other proteins or protein fragments and other contaminants such as cell debris, or residual impurities from other purification steps	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: col. 3:53-61.	Mylan contends that no construction is necessary and that this term should be afforded only its plain and ordinary meaning. To the extent Amgen offers proposed constructions for any terms or phrases which differ from the person of ordinary skill in the art's understanding of the plain and ordinary meaning of any of the terms or phrases, Mylan reserves the right to offer alternative construction(s). (Shortened below to "plain and ordinary	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: 3:53-64

[3] Mylan reserves the right to assert additional evidence in rebuttal to Amgen's proposed constructions during briefing. To the extent Mylan is permitted to assert additional evidence in rebuttal to Amgen's proposed constructions, Amgen may present additional evidence in reply. The parties further intend to rely on the patents-in-suit, the specifications of the patents-in-suit, the claims of the patents-in-suit, the file histories of the patents-in-suit, and patents and applications to which the patents-in-suit claim priority, including related patents or patent applications. Any additional evidence or reference within or encompassed by a particular citation is deemed incorporated by reference (e.g., references to a figure or table are incorporated by reference).

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
			meaning; no construction necessary") Alternatively, if construction is required: "a column containing a stationary phase or resin and a mobile or solution phase in which the hydrophobic interaction between a protein and hydrophobic groups on the matrix serves as the basis for separating a protein from impurities including fragments and aggregates of the subject protein, other proteins or protein fragments and other contaminants such as cell debris, or residual impurities from other purification steps."	
such that the **dynamic capacity** of the column is increased for the protein	the maximum amount of protein in solution which can be loaded onto a column without significant breakthrough or leakage of the protein into the solution phase of the column before	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: col. 3:65–4:16.	Plain and ordinary meaning; no construction necessary Alternatively, if construction is required: "the maximum amount of protein in solution which can be loaded onto a column without significant	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: 3:65-4:3

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
	elution		breakthrough or leakage of the protein into the solution phase of a column before elution."	
such that the dynamic capacity of the column is increased for the protein	such that the dynamic capacity of the hydrophobic interaction chromatography column for the protein that is achieved by using a combination of a first salt and a second salt, each at a reduced concentration compared to the concentration of either salt when used alone, is greater than the dynamic capacity of the column for the protein that is achieved by using a single salt at a higher concentration	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: col. 3:31-40; 4:46-51; 12:37-40; 13:59-64; 14:42-44, 62-63.	Plain and ordinary meaning; no construction necessary	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: Abstract; 2:39-42; 3:37-40
comprising **mixing a preparation**	forming the mobile, or solution, phase, which	**'707 Patent** MYL(PegF)0145124-	Plain and ordinary meaning; no construction necessary[4]	**'707 Patent** MYL(PegF)0145124-38, including but not

[4] Subject to Amgen's prosecution disclaimer as fully briefed in Mylan's Motion for Judgment on the Pleadings Pursuant to Rule 12(c) (ECF Nos. 79, 81, 97).

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
containing the protein with a combination of a first salt and a second salt,	contains the protein, a first salt, and a second salt	38, including but not limited to: 3:53-61; 4:23-29, 46-51.		limited to: Abstract; 2:39-42; 6:54-67; 7:20-22; 12:45-65 **'707 Patent Prosecution History** MYL(PegF)0145139-359, including but not limited to: 1/26/2011 Response to Office Action at 5-7 (MYL(PegF) 0145243-45); 1/20/2011 Decl. of A. Senczuk at 2-3 (MYL(PegF) 0145247-48); 8/22/2011 Amendment after Final at 5-6 (MYL(PegF) 0145291-92) **'707 Parent Prosecution History** MYL(PegF)0168830-9088, including but not limited to: 7/14/2008 Response to Office Action at 3-9

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
				(MYL(PegF) 0168973-79
loading the mixture onto a hydrophobic interaction chromatography column, and	causing the protein in the mobile phase to contact the hydrophobic groups on the matrix	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: col. 3:9-19.	Plain and ordinary meaning; no construction necessary	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: Abstract; 1:66-2:4; 3:16-19; 4:27-29; 4:56-60; 6:54-67; 12:45-13:1 **'707 Parent Prosecution History** MYL(PegF)0168830-9088, including but not limited to: 7/14/2008 Response to Office Action at 5-9 (MYL(PegF) 0168975-79)
eluting the protein,	Not Disputed; Provided for Context			
wherein the first and second salts are selected from the	Not Disputed; Provided for Context			

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively, and				
wherein the concentration of each of the first salt and the second salt in the mixture is **between about 0.1 M and about 1.0**.	approximately 0.1 M to approximately 1.0 M, depending on the characteristics of the particular salt	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: col. 3:31-36; 6:8-10; Ex. 1 and 2.	Plain and ordinary meaning; no construction necessary	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: 2:30-33; 3:20-36; 6:8-14; Table 1; Table 2; 13:64-14:5 **'395 Parent Patent Prosecution History** MYL(PegF)0168830-9088, including but not limited to: 4/13/2007 Response to Restriction Requirement at 3-5 (MYL(PegF) 0168910-12); 7/14/2008 Response to Office Action at 5-9 (MYL(PegF) 0168975-79)

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
8. The process of claim 1, further comprising **formulating the protein**.	formulating the protein for pharmaceutical use as a biologic	**'707 Patent** MYL(PegF)0145124-38, including but not limited to: col. 7:56-58; 10:4-32.	Plain and ordinary meaning; no construction necessary	
10. A method of increasing the dynamic capacity of a **hydrophobic interaction chromatography column** for a protein,	Same Construction as in Claim 1		Mylan incorporates by reference its response and intrinsic evidence cited for this phrase with respect to claim 1.	
10. A method of increasing the **dynamic capacity** of a hydrophobic interaction chromatography column for a protein,	Same Construction as in Claim 1		Mylan incorporates by reference its response and intrinsic evidence cited for this phrase with respect to claim 1.	
10. A method of **increasing the dynamic capacity**	increasing the dynamic capacity of a hydrophobic interaction chromatography	**'707 Patent** MYL(PegF)0145124-38, including but not	Plain and ordinary meaning; no construction necessary	**'707 Patent** MYL(PegF)0145124-38, including but not

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
of a hydrophobic interaction chromatography column for a protein,	column for a protein that is achieved by using a combination of a first salt and a second salt, each at a reduced concentration compared to the concentration of either salt when used alone, compared to the dynamic capacity of the hydrophobic interaction chromatography column for the protein that is achieved by using a single salt at a higher concentration	limited to: col. 3:31-40; 4:46-51; 12:37-40; 13:59-64; 14:42-44, 62-63.		limited to: Abstract; 2:39-42; 3:37-40
comprising **mixing a preparation containing the protein with a combination of a first salt and a second salt**,	Same Construction as in Claim 1		Mylan incorporates by reference its response and intrinsic evidence cited for this phrase with respect to claim 1.	
and **loading the mixture onto a hydrophobic interaction chromatography**	Same Construction as in Claim 1		Mylan incorporates by reference its response and intrinsic reference cited for this phrase with respect to claim 1.	

Claim Term or Phrase (in Bold)	Amgen's Proposed Construction	Amgen's Citation to Intrinsic Evidence	Mylan's Proposed Construction	Mylan's Citation to Intrinsic Evidence
column,				
wherein the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate and sulfate and acetate, respectively,	Not Disputed; Provided for Context			
and wherein the concentration of each of the first and second salts in the mixture is **between about 0.1 M and about 1.0 M**.	Same Construction as in Claim 1		Mylan incorporates by reference its response and intrinsic reference cited for this phrase with respect to claim 1.	